REMARKS

This document is filed in reply to the office action dated June 30, 2003 ("Office Action"). Applicant has amended claims 8-11 to present them in independent form. Applicant has also incorporated into claim 11 the limitation of claim 12, which has necessitated the cancellation of claims 12, 19, and 24, and the dependency change of claim 13. Finally, Applicant has added claims 35-46. Support for the newly claims can be found in original claims 2-4. No new matter has been introduced.

Claims 1-11, 13-18, 20-23, and 25-46 are pending. Claims 1-7 and 26-34 have been withdrawn from further consideration for being drawn to a non-elected invention. Claims 8-11, 13-18, 20-23, 25, and 35-46 are now under examination. Reconsideration of this application is requested in view of the following remarks:

Rejection under 35 U.S.C. § 101 and § 112, first paragraph

The Examiner rejected claims 8-25 for lack of utility. More specifically, it is the Examiner's position that "the claimed invention is not supported by either a substantial asserted utility or a well established utility. " See page 2, lines 9-10 of the Office Action.

Applicant has cancelled claims 12, 19, and 24, and will discuss the other rejected claims below. Claim 8 is discussed first. This claim is drawn to a nucleic acid that encodes a polypeptide which (1) contains an amino acid sequence at least 70% identical to SEQ ID NO:2 and (2) binds to an androgen receptor and increases the ability of the androgen receptor to transactivate an androgen-responsive gene. The specification points out that the nucleic acid is over-expressed in hepatocellular carcinoma cells and therefore can be used to diagnose liver cancer. See page 5, line 31 through page 6, line 9 of the specification. Further, the specification teaches that the polypeptide encoded by the nucleic acid, e.g., androgen receptor complex-associated protein (or ARCAP protein), can be used as a cancer drug target. That is, a compound that inhibits the activity of ARCAP protein can be used to treat cancer. See page 6, line 20 through page 7, line 5. Accordingly, the specification has asserted a substantial utility of the nucleic acid.

Nonetheless, the Examiner asserted that "there is no nexus between the unknown properties of the [ARCAP] protein and the treatment of cancer." Contrary to his assertion, as shown in a Declaration by Tai-Jay Chang (attached as "Exhibit A"), ARCAP protein promotes the anchorage-independent growth of mouse liver oval WB1A cells and the growth of hepatoma A2 cells. The results indicate that ARCAP protein promotes tumorigenesis. It follows that a compound that inhibits this activity of ARCAP protein can treat cancer. Clearly, ARCAP protein and an analogue polypeptide having the same activity are useful as cancer drug targets. Therefore, a nucleic acid of claim 8 that encodes such a polypeptide is useful.

Claim 9 covers a nucleic acid that encodes a polypeptide which contains SEQ ID NO: 2, i.e., the sequence of ARCAP protein. Claim 10 is drawn to a nucleic acid encoding a polypeptide having the sequence of SEQ ID NO: 2 with up to 30 conservative amino acid substitutions. Claim 11 covers a nucleic acid that has a strand that hybridizes under stringent conditions to a single stranded probe consisting of SEQ ID NO:1 or the complement of SEQ ID NO:1. The nucleic acids of claims 10 and 11 all encode polypeptides having the activity of ARCAP protein. Claims 13-14, dependent from claim 11, are drawn to nucleic acids that encodes a polypeptide containing SEQ ID NO: 2, and is at least 15 nucleotides in length, respectively. All the nucleic acids encode polypeptides that either have the sequence or the activity of ARCAP protein. For the same reasons set forth above, the nucleic acids of these claims are also useful.

Claims 15-18, 20-23, 25, and 35-46 are drawn to vectors and cultured cells containing the above-mentioned nucleic acids, and methods of producing polypeptides encoded by the nucleic acids. As the polypeptides and the nucleic acids are useful, these claims also meet the utility requirement.

The Examiner further rejected claims 8-25 for lack of enablement, contending that since these claims do not meet the utility requirement, "one skilled in the art clearly would not know how to use the claimed invention." See page 3, lines 10-13 of the Office Action. As set forth above, all the claims meet the utility requirement. Thus, grounds for the rejection have also been overcome.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 11, 14, 18, and 23 for indefiniteness. It is his position that the phrase "hybridizes under stringent conditions" recited in claim 11 is ambiguous. See the Office Action, page 4, lines 4-6. Applicant would like to point out the specification has clearly defined the meaning of the phrase. See page 4, last paragraph. The rejection therefore should be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 11, 14, 18, and 23 for lack of written description. More specifically, he contended that "[t]he claims encompass nucleic acid molecule[s] encoding variants whose structure is not known or nucleic acid molecules encoding other variant proteins with different function from SEQ ID NO: 2..." See the Office Action, page 4, lines 7-18.

Claim 11 is discussed first. This claim, as amended, covers an isolated nucleic acid that (1) contains a strand that hybridizes under stringent conditions to a single stranded probe, the sequence of which consists of SEQ ID NO:1 or the complement of SEQ ID NO:1, and (2) encodes a polypeptide that binds to an androgen receptor and increases the ability of the androgen receptor to transactivate an androgen-responsive gene.

Applicant submits that the specification provides sufficient written description for claim 11, as evidenced by the U.S. Patent and Trademark Office's own guidelines on the subject: Synopsis of Application of Written Description Guidelines, www.uspto.gov/web/menu/written.pdf ("Guidelines"). Example 9 of the Guidelines illustrates a hypothetical situation that mirrors the present case. Just as in Example 9, claim 11 is drawn to an "isolated nucleic acid that hybridizes to SEQ ID NO: 1 [or its complement] under highly stringent conditions and encodes a protein with a specific function. Just as in Example 9, "[t]he claim is drawn to a genus of nucleic acids all of which must hybridize with SEQ ID NO: 1 and must encode a protein with a specific activity." Furthermore, just as in Example 9, "[t]here is a single species disclosed (a molecule consisting of SEQ ID NO: 1) that is within the scope of the

claimed genus" and "[t]here is actual reduction to practice of the disclosed species." Example 9 then provides the following guidance to examiners:

> "Now turning to the genus analysis, a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claim because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention.
> **Conclusion:** The claimed invention is adequately described."

In view of the very clear instructions from the Guidelines and the teachings in the Specification, Applicant submits that claim 11, as well as claim 14, 18, and 23, which depend from claim 11, meets the written description requirement.

Priority

The present application claims priority from U.S. Application 60/262,312 (" '312 application"). Nonetheless, the Examiner declined this claim, alleging that the '312 application "fails to provide adequate support under 35 U.S.C. § 112" for claims 8-25. See the Office Action, page 5-7.

Applicant respectfully traverses. Claims 8-11, 13, and 14 of this application cover the nucleic acids described above. Support for the claims can be found at page 3, lines 24-41 of the '312 application. The specification has further provided examples for the claimed nucleic acids, e.g., SEQ ID NO: 1 and SEQ ID NO: 3. Claims 15-18, 20-23, 35-46 of the present application cover vectors and cultured host cells containing the above-described nucleic acid, and methods of producing polypeptides encoded by the nucleic acids. Support for these claims can be found at page 3, line 36 through page 4, line 3 of the '312 application; working examples for the claimed vector, host cell, and method can be found at page 24, lines 21-27. Therefore, all of the claims are supported by the '312 application and entitled to the benefit of its filing date.

Rejection under 35 U.S.C. § 102(a)

The Examiner rejected claims 8, 10-12, 14, 15, 17-20, and 22-25 for being anticipated by Hillman et al. (WO 01 07417, "Hillman"). See the Office Action, page 6, lines 1-2.

As mentioned above, all the claims at issue are entitled to the benefit of the filing date of the '312 application, i.e., January 17, 2001, which is prior to the publication date of Hillman, February 1, 2001. Therefore, Hillman is not citable against the present application, and the rejection should be withdrawn.

CONCLUSION

Applicant submits that grounds for the rejections asserted by the Examiner have been overcome, and that claims, as pending, define subject matter that is useful, definite, sufficiently described, and novel. On this basis, it is submitted that allowance of this application is proper, and early favorable action is solicited.

Enclosed is a $81 check for excess claim fees. Please apply any other charges to deposit account 06-1050.

Respectfully submitted,

Date: 9-30-03

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